Message

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]
Sent: 8/13/2016 1:30:08 PM
To: Cogliano, Vincent [cogliano.vincent@epa.gov]; Burke, Thomas [Burke.Thomas@epa.gov]; Deener, Kathleen [Deener.Kathleen@epa.gov]; Kavlock, Robert [Kavlock.Robert@epa.gov]; Slimak, Michael [Slimak.Michael@epa.gov]; Thomas, Russell [Thomas.Russell@epa.gov]; Flowers, Lynn [Flowers.Lynn@epa.gov]; Gwinn, Maureen [gwinn.maureen@epa.gov]; Ross, Mary [Ross.Mary@epa.gov]; Vandenberg, John [Vandenberg.John@epa.gov]
BCC: Bahadori, Tina [Bahadori.Tina@epa.gov]
Subject: Third Party Assessments, Again, relevant to our Innovations In Chemical Risk Assessment Discussions?

And yesterday FDA announced its decision to accept 'third-party' GRAS evaluations, in order to increase the efficiency of their safety assessments (article below). This is also a consideration under new TSCA:

==========

FDA: Food Additive Reviews Stronger With Voluntary Notice

Snapshot

• FDA releases final rule on voluntary risk reviews of food additives, arguing it's effective and efficient
• Food safety advocates take issue with allowing industry to conduct its own safety evaluations

By Steven Gibb

Aug. 12 — After blocking partially hydrogenated oils and caffeinated alcoholic beverages, the Food and Drug Administration says its final rule allowing outside groups to evaluate food additive risks will streamline its "Generally Recognized as Safe" reviews.

The agency released its GRAS final rule (RIN:0910-AH15) Aug. 12 for its food additive program, switching reviews from a more formal but slower "petition-based" process to a voluntary "notification" process, which it says establishes "uniform criteria for describing the basis for a conclusion that a substance is GRAS under the conditions of its intended use."

According to the FDA's review of its notification pilot program, "experience also has shown that streamlining our evaluation of conclusions of GRAS status will enable us to evaluate more, and higher priority, substances."

But the change has prompted swift reaction from food safety advocates, who say industry should not be allowed to convene their own GRAS panels and then submit the results to the agency.

Trade-Off?

"FDA should not trade effective regulation for efficient regulation," said Cristina Stella, an attorney with the nonprofit advocacy group the Center for Food Safety. "We're taking a close look at the final rule and evaluating our legal options," she said.

The agency points to its treatment of partially hydrogenated oils and caffeinated alcoholic beverages as evidence the voluntary GRAS pilot notification program was, and will continue to be, effective.

The agency states that there "is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food," and that it "informed the companies who were marketing these caffeinated alcoholic beverages that caffeine, as used in the companies' products, is an unsafe food additive, and therefore the products are adulterated."

The FDA also states that since 1998, it has processed 638 GRAS notices, compared to the previous decade where the agency issued 25 GRAS affirmation petitions.

Under the former petition-based process the agency would publish an order in the Federal Register listing the substance as GRAS, and issue a corresponding regulation that prescribes the safe conditions of its use. If it determined that it was not GRAS, then the agency would notice that in the Federal Register.

Advocates Preferred Petition Process
Stella says advocates preferred the former process, saying at least "it required more on the part of FDA and industry" to ensure a safe food supply.

And Jessica Almy, deputy director of nutrition policy at the Center for Science in the Public Interest, says the final rule is "deeply disappointing in that they've had 19 years to address this and still haven't gotten to critical conflict of interest ground rules for industry's secret safety determinations."

Agency spokesperson Lauren Sucher says "FDA can question the basis for an independent GRAS conclusion and take action as appropriate. The FDA has the authority to review and evaluate data on substances added to food in order to ensure safety."

And the agency also asserts that its scientific criteria for quality data are more rigorous and transparent than under the previous program. "Unless both criteria, i.e., 'generally available' as well as 'generally accepted', are satisfied, there would be no basis for a conclusion of GRAS status." It also eliminated the need for complete agreement among risk reviewers in the final rule, compared with the proposed rule.

The final rule "uses the term 'generally recognized' rather than the term 'consensus,'" according to the agency.

Calls to the Grocery Manufacturers Association for comment were not returned.

To contact the reporter on this story: Steve Gibb in Washington at sgibb@bna.com
To contact the editor responsible for this story: Larry Pearl at lpearl@bna.com

From: Cogliano, Vincent
Sent: Friday, August 12, 2016 9:17 AM
To: Burke, Thomas <Burke.Thomas@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Deener, Kathleen <Deener.Kathleen@epa.gov>; Kavlock, Robert <Kavlock.Robert@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Subject: RE: Relevant to our Innovations In Chemical Risk Assessment Discussions?

Ex. 5 Deliberative Process (DP)

From: Burke, Thomas
Sent: Friday, August 12, 2016 9:10 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Cc: Deener, Kathleen <Deener.Kathleen@epa.gov>; Kavlock, Robert <Kavlock.Robert@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Flowers, Lynn <Flowers.Lynn@epa.gov>; Gwinn, Maureen <gwinn.maureen@epa.gov>; Ross, Mary <Ross.Mary@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>
Subject: Re: Relevant to our Innovations In Chemical Risk Assessment Discussions?

Thank you Tina. Very informative.

Sent from my iPhone

On Aug 12, 2016, at 7:48 AM, Bahadori, Tina <Bahadori.Tina@epa.gov> wrote:

I thought Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

==========

Daily News

Chemical Sector, Advocates Clash Over Using IRIS For TSCA Risk Reviews

August 11, 2016

Chemical producers and environmentalists are clashing over whether EPA should use its controversial Integrated Risk Information System (IRIS) chemical assessments when conducting new substance reviews mandated by the Toxic Substances Control Act (TSCA) reform law, with industry fighting advocates' call to weigh the IRIS values.

EPA held an Aug. 10 meeting in Washington, D.C., to take input from stakeholders on how to craft a proposed rule under the new law that will establish a risk-based process for prioritizing chemical risk reviews. The agency also held an Aug. 9 meeting on developing a separate proposal for assessing whether a chemical presents an unreasonable risk to human health or the environment, and an Aug. 11 meeting on how to collect industry fees under the law.

At the Aug. 9 meeting, chemical industry officials warned EPA officials against utilizing IRIS assessments in risk evaluations performed under EPA's new TSCA authorities while advocates called for the agency to consider aspects of the overhauled IRIS program as it pursues the TSCA mandates for reviewing chemicals.

EPA's Office of Research & Development uses the IRIS program to assess chemicals' human health risks, and the values are often used as the basis for agency rulemakings. The program has faced criticism over claims that it 'cherry picks' the data it uses and its conservatism. EPA has sought to improve IRIS' scientific rigor, transparency and production following a critical National Academy of Sciences review in 2011 of a draft assessment of formaldehyde.

Since then, the agency has taken a number of steps such as launching a new dedicated federal advisory panel, and re-formatting how it conducts the assessments. But some scientific efforts, such as adopting an information gathering and assessing methodology known as systematic review, remain in progress and production has further dwindled. The IRIS program last finalized an assessment in December 2014 -- a concern of the House science and oversight committees, which have launched recent inquiries into its status.

Chemical industry officials at the Aug. 9 meeting urged EPA against incorporating values from IRIS in the TSCA reform law-mandated chemical reviews. The suggestion is line with industry's frequent criticisms of IRIS for producing overly-conservative human health risk estimates. Still, the IRIS assessments are often considered EPA's most rigorous, taking years to complete and undergoing extensive public comment and peer review.

Industry's Concerns

"EPA will likely to be tempted . . . to rely on information from existing databases. However, I caution you that the requirements of the new statute make this very hard," in its chemical evaluations, said Nancy Beck, a senior director with the chemical industry association American Chemistry Council.

"It's well known that the IRIS program has struggled for years to produce high quality assessments," Beck said. "While the IRIS program is working to address these problems, to date it has not finalized a single assessment that is fully consistent with the NAS recommendations" in the 2011 formaldehyde report, which contained a rare chapter outside its charge containing general recommendations on how to improve IRIS assessments.

"The justification that it's in IRIS will simply not suffice for the new act," Beck said. "Grabbing studies from IRIS may be appropriate for your screening level assessments, but for your refined hazard assessments, we think you'll need to conduct a new weight of the evidence review."

Other industry officials seconded Beck's call, including a Shell representative who said language in section 17 of the new law requiring EPA to utilize "best available science" and to base decisions on the "weight of scientific evidence" suggests caution against using values from IRIS assessments and other existing assessments in upcoming TSCA reviews.

Industry representatives may be particularly concerned about the toxics office's use of IRIS assessments because of its 2014 work plan risk assessments of the solvent and degreaser trichloroethylene (TCE). EPA's work plan program, launched in 2012, is an effort to assess chemicals under prior TSCA authority and was also intended to prepare agency staff for new chemical management responsibilities should Congress overhaul TSCA.

At the Aug. 10 EPA meeting, Halogenated Solvents Industry Alliance (HSIA) attorney Caffey Norman outlined long-standing concerns with EPA's use of a contested 2011 IRIS TCE review in a 2014 work plan assessment.

The 2011 TCE IRIS assessment was highly controversial because of the strict risk calculation it contained, based on a study of fetal cardiac defects which HSIA argues is poorly conducted and should not be used in the IRIS assessment. Industry has said EPA should not use what it argues is a short-term effect to calculate chronic risk values.

HSIA has since filed Data Quality Act challenges against both the IRIS assessment and the risk assessment based on it, seeking to have them withdrawn, though the agency has so far declined to do so.

IRIS Program

However, environmentalists and other stakeholders at the meeting encouraged EPA to consider the steps the agency has taken to reform and improve the IRIS program as it develops the new TSCA reviews.

"It's critical that EPA do thorough, modern risk evaluations," said Jen Sass, a senior scientist at the Natural Resources Defense Council. She recommended that EPA also weigh recommendations in several NAS reports, including a 2009 report called "Science and Decisions: Advancing Risk Assessment."

She pointed specifically to the recommendation in a 2014 report to the IRIS program recommending that it adopt a systematic review-type approach, under which scientists gather data and evaluate it based on pre-determined scientific questions and related criteria, while transparently documenting their decisions. "I want to elevate some of those recommendations -- first, systematic review," Sass said. "We've very impressed by what [the National Toxicology Program] and IRIS are doing" with systematic review.

Sass and other stakeholders also encouraged EPA's toxics managers to consider other recommendations that recent NAS reports have made to the IRIS program. These include using science-based defaults rather than being paralyzed in the assessment process by lack of chemical-specific data, treating carcinogens and non-carcinogens alike in assessment practices and using probabilistic risk assessment practices for non-carcinogens. Probabilistic risk assessments are traditionally used when assessing carcinogens, allowing risk managers to review a range of risks at specific levels of exposure to chemicals.

Tracey Woodruff, a professor at the University of California San Francisco's medical school, also urged the toxics leaders to look to recommendations in Science and Decisions, as well as the 2014 NAS review of the IRIS program, and a 2010 NAS report on phthalates and cumulative risk assessment. "Those provide a good blueprint," she said.

More particularly, Woodruff urged EPA's toxics office to consider treating cancer and non-cancer health endpoints as equals in weight of evidence and risk evaluations," to "not assume there is a threshold response in non-carcinogens," and not to use an approach called margin of exposure in its evaluations.

Risk Evaluations

EPA has traditionally placed greater weight on carcinogenic risks, and it has traditionally assessed the risks of carcinogens and non-carcinogens differently, often assuming that there is not safe level of exposure to carcinogens while assuming that there is for non-carcinogens. As a result, EPA uses probabilistic approaches to assess the risks of carcinogens while it does not for non-carcinogens. This makes it difficult for the agency to act based on non-cancer assessments, because they do not provide the information necessary for cost-benefit analysis.

The margin of exposure approach that EPA has used in its TSCA work plan program -- an effort launched in 2012 to assess some chemicals under prior TSCA authority -- and also often uses in its pesticides office, is also not probabilistic and again, does not provide crucial cost-benefit information for risk managers, Woodruff said.

The new statute encourages EPA to use the work plan program as a bridge to the new programs it will implement per the agency's new authorities. The statute allows EPA to rely on completed work plan assessments as the basis for TSCA rules and directs the agency to select some of its first chemicals for assessment in the new program from the list of 90 chemicals EPA prioritized for assessment in the work plan program.

Gina Solomon, deputy secretary for science and health at California's EPA, also encouraged EPA to adopt the probabilistic risk analysis approaches recommended in the NAS' Science and Decisions report, and to avoid what she called a "no data, no risk trap," of not acting when there is limited data to conduct a risk analysis. -- *Maria Hegstad* (mhegstad@iwpnews.com)